Vaginal packing after vaginal hysterectomy with or without colporrhaphy: systematic review and recommendations.

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Abstract

Background. Vaginal packing is often used after vaginal hysterectomy to reduce the risk of haemorrhagic and infectious complications, but the procedure may impair spontaneous bladder emptying and necessitate permanent bladder catheterization that itself increases the risk of urinary infection, patient bother, delayed discharge, and increased costs. Objectives. This systematic review aimed to assess the complications and outcomes associated with vaginal packing after vaginal hysterectomy (with or without colporrhaphy). Search Strategy. We conducted a systematic review following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) Statement. Selection Criteria. We used the Population, Interventions, Comparators, Outcomes, and Study design (PICOS) framework to define eligibility. Predefined outcomes were: i) vaginal bleeding and blood loss, ii) postoperative pain, iii) acute urinary retention, iv) hospital length of stay, and v) mid-term complications, such as vaginal cuff collection or infection. Data Collection and Analysis. Following data synthesis and subgroup analyses, we assessed the certainty of evidence according to GRADE guidance and formulated a clinical recommendation. Main Results. The review included four clinical trials (involving 337 participants). These provided no clear evidence that vaginal packing led to clinically meaningful reductions in adverse effects, such as vaginal bleeding, hematoma formation, or postoperative vaginal cuff infection. Overall, the intervention produced no clear benefit on the predefined outcomes. Conclusions. Routine vaginal packing after vaginal hysterectomy had no clear benefit on outcomes. We therefore advise against this procedure. Funding. The Catalan Society of Obstetrics and Gynaecology granted funding to conduct this work.

1. Introduction

Vaginal hysterectomy is a common surgical procedure that approximately one in ten women will have undergone by age 80 years (1). Moreover, given the ageing population, rates of uterovaginal prolapse and surgical intervention could increase by almost 50% by the year 2050 (2). As with any procedure, vaginal hysterectomy can produce complication, and traditionally, vaginal packing has been used to reduce the risk of haemorrhagic (e.g., vaginal bleeding and/or hematoma) and infectious (e.g., vaginal cuff abscess formation) complications. However, vaginal packing may impair spontaneous bladder emptying and usually necessitates the placement of a permanent bladder catheter (most often with a Foley catheter) at the time of packing. This, in turn, increases the risk of urinary infection, patient bother, and delayed discharge, and it negatively affects costs (3,4). Therefore, care is required when evaluating the need for packing. Though the duration of packing has apparently shortened in the recent years, consensus has not been reached on the suitability and optimal use of this intervention due to insufficient evidence.

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The aim of this systematic review was to compare the complications and outcomes between interventions that use and do not use vaginal packing after vaginal hysterectomy with or without colporrhaphy.

2. Materials and methods

2.1. Study design

We performed a systematic review to determine whether routine vaginal packing after vaginal hysterectomy affected postoperative complications. The review findings informed the formulation of a recommendation using an explicit and reason-working framework. Specifically, we reviewed the literature according to the Cochrane Collaboration guidance (5) and reported our findings according to the PRISMA statement (6). We used the Population, Interventions, Comparators, Outcomes, and Study design (PICOS) framework to define eligibility. The review protocol was not registered. The Catalan Society of Obstetrics and Gynaecology granted funding to conduct this work. No ethical approval was necessary.

2.2. Research question

The review sought to answer the clinical question, "What is the impact of routinely packing the vagina after vaginal hysterectomy?" The inclusion criteria limited eligibility to randomized clinical trials of women undergoing vaginal hysterectomy for any reason (with or without colporrhaphy) by whether they were allocated to receive routine vaginal packing postoperatively. We addressed the impact of the intervention on predefined outcomes: i) vaginal bleeding and blood loss, ii) postoperative pain, iii) acute urinary retention, iv) hospital length of stay, and v) mid-term complications, such as vaginal cuff collection or infection.

2.3. Search strategy

The search strategy obtained relevant studies from MEDLINE (accessed via PubMed), EMBASE (accessed via embase.com), and CENTRAL up to March 2022. We combined text words and controlled vocabulary from the databases, without placing limits on the year of publication or language (see supplementary material for the complete search criteria), and we completed the search by checking the list of references from relevant studies. The search results were placed in a database to coordinate eligibility assessments, which was completed by two authors independently who discussed any disagreements with the other authors.

2.4. Data analysis

One reviewer extracted descriptive characteristics and effect estimates for each outcome of interest from the included studies and recorded them on a data extraction form, which the remaining authors verified for accuracy. Risk of bias for each included study was assessed in selection, performance and attrition bias (5). We described the review findings narratively for each predefined outcome, and when feasible, pooled the effect estimates in a random effects meta-analysis according to the DerSimonian and Laird method (5). RevMan (Review Manager (RevMan) [Computer program]. Version 5.4. The Cochrane Collaboration, 2020) was used to conduct these analyses.

To obtain an explicit judgement on the confidence in the review findings, we classified the quality of evidence for each outcome as high, moderate, low, or very low according to the GRADE working group guidance (7). We also integrated judgements on the quality of the evidence into a summary of findings table (8), which included the effect estimates for the outcomes of interest.

2.5. Recommendations

An evidence-to-decision (EtD) framework was used to formulate an explicit and reasoned recommendation, integrating the determinants, that defined the direction and strength (9). To complete this process, we considered results from economic evaluations and from studies on perceptions and experiences with the findings from the systematic review.

3. Results

3.1. Descriptive analysis

We identified 97 unique references from the search and assessed seven studies according to the inclusion criteria. One non-randomized study (10) and two studies that assessed combined interventions (11,12) were excluded. Finally, four clinical trials involving 337 participants were included. Figure 1 shows the PRISMA flow diagram detailing this process and Table 1 provides an outline of the main characteristics from the included trials. We obtained data from two trials, which included women undergoing similar surgical procedures and receiving similar postoperative care, exclusively from conference abstracts (13,14). The other two trials assessed pain as the main outcome (15,16), and one of these also assessed postoperative blood loss (16). The risk of bias from the trials varied, and of note, the trials reported as conference abstracts provided little detail on their study design but were described as randomized (13,14). Risk of selection bias was low in the other two trials, which also implemented strategies to blind the participants and the staff responsible for the outcome evaluation (15,16).

3.2. Impact of routine vaginal packing after vaginal hysterectomy

Vaginal packing may have little or no effect on vaginal bleeding. In a study involving 77 women, postoperative blood loss was greater in the group receiving vaginal packing (median, 16 [interquartile range, 13.4] g) compared with the control group (5 [8.2] g; p < 0.01) (15). In another study involving 173 participants, the rate of vaginal bleeding was similar among groups (one outcome without packing, relative risk [RR] = 0.34; 95%CI 0.14–8.16) (16).

Vaginal packing probably does not affect postoperative pain, with one study reporting no differences in postoperative pain visual analogue scale (VAS) scores in either the early postoperative period or before discharge. Differences in pain scores among groups did not reach the minimal relevant difference used in the sample size calculation (14 mm): in the immediate postoperative period, a median of 41.6 (25.7) in the packing group versus 46.3 (26.2) in the control group; and at discharge, a median 35.0 (36.0) in the packing group versus 40.0 (39.0) in the control group. More women in the control group needed ketorolac analgesia (median 15 mg [SD 45 mg] in women with packing versus 45 mg [SD 75 mg] in women without [p < 0.001]) (15). Another study did not show differences in McGill Pain Questionnaire scores the morning after the surgical procedure (median 11 [rank IQ, 3–18] in the packing group versus 10 [rank IQ, 4–16] in the control group) (16). Finally, a third trial did not show differences in VAS scores 24 h after the surgical procedure (median 1.0 [1.9] in the packing group versus 0.81 [1.5] in the control group) (13).

Vaginal packing likely does not increase the risk of haematoma. Combined analysis of the three trials describing haematoma as the outcome revealed no statistically significant differences among the studied groups. However, haematomas were more frequent in the group without packing (3.3% versus 6.7%; RR 0.53, 95%CI 0.22–1.31). These results should be considered imprecise given that approximately 450 adverse events would have been necessary to find a significant reduction.

A study involving 173 participants showed a trend towards a greater risk of vaginal haematoma in the no packing group, although differences were not significant (4/86 versus 9/87; RR 0.44, 95%CI 0.14–1.37); 2 of these cases corresponded to an infected vaginal cuff haematoma. This study also showed similar proportions of women suffering from urinary infection in each group (9.3% versus 10.3%; RR 0.88, 95%CI 0.35–2.17) (16). In another study involving 43 women, a non-statistically significant greater proportion of women without packing also developed a haematoma (9.1% versus 19.1%; RR 5.0, 95%CI 0.25–98.27). This study further revealed a greater proportion of women with urinary tract infection in the packing group (not significant, 9.1% versus 0.0%; RR 0.23, 95%CI 0.03–1.96) (14). Finally, a study of 144 women also showed a non-significantly greater proportion of women with haematoma in the group without packing (0.0% versus 4.28%; RR 0.13, 95%CI 0.01–2.57) (13).

3.3. Recommendation

Table 3 shows the EtD framework that we discussed to formulate a recommendation. We recommend against routinely placing a vaginal pack after vaginal hysterectomy with or without colporrhaphy. This was a conditional recommendation because packing likely results in little or no benefit in terms of vaginal bleeding and other postoperative complications or pain, indicating that routine care should favour minimal

intervention. However, although the available evidence was not consistent, we observed a trend towards an increased rate of hematomas in the mid-term when packing was not used. For that reason, we emphasize that it may be appropriate to consider the intervention if haemostasis cannot be confirmed during the surgical procedure. We also considered indirect data from Enhanced Recovery After Surgery (ERAS) pathways, which often exclude vaginal packing and show that this approach may shorten hospitalization, lead to fewer readmissions, and reduce costs (18–20).

4. Discussion

4.1. Main findings

There was no clear evidence that vaginal packing was associated with clinically meaningful reductions in adverse effects such as vaginal bleeding, hematoma formation, or postoperative vaginal cuff infection.

With regards to vaginal bleeding, Westerman et al. (15) found a difference in postoperative vaginal blood loss of about 11 g between groups, which was statistically significant but clinically irrelevant. When a decrease in haemoglobin was considered, both Westerman (15) and Thiagamoorthy (16) found no significant differences among these groups.

As for vault hematoma formation, results from three studies (Thiagamoorthy, Baumgarten, Urzua) indicated a trend towards higher incidence of vaginal hematoma as a mid-term complication when the vagina was not packed, although differences were not statistically significant. The studies by Yoong (18) and Ottesen (21), evaluating fast track protocols, showed no differences in relevant outcomes between women with and without vaginal packing. Moreover, in the systematic reviews by Jeppson (22) in 2017 and Rachaneni (23) in 2018, vaginal packing was not recommended as a preventive measure against vault hematoma, whereas Ottesen (21) suggested that the vagina could be packed only when the surgeon deemed it necessary.

Thiagamoorthy studied postoperative vaginal cuff infection by microscopic analysis and found no differences between the groups with and without packing (16). A case-control study by Yoong also found no difference on this outcome (18). Furthermore, both Jeppson's review (22) and our analysis concluded that there was no difference in the incidence of vaginal cuff infection based on moderate-quality evidence.

Vaginal packing did not affect patient bother or postoperative pain significantly. We aimed to assess whether vaginal packing was associated with increased postoperative pain or discomfort in comparison with no vaginal packing. In all three studies evaluating pain, the variable was analysed using the pain VAS or the McGill Pain Questionnaire, but none reported a statistically significant difference between the two groups. The study by Westermann (15) reported a significant increase in the number of complaints expressed verbally to nurses by patients not wearing vaginal packing compared to those wearing tampons. In the same study, an increased demand for ketorolac was quantified in the vaginal packing group, though without a statistically significant difference. In addition to these findings, there was insufficient information on the type of anaesthesia during surgery to make comparisons between groups based on this variable. Among the patients who participated in the studies, the higher observed rate of complications in patients who did not use vaginal packing probably translated into greater pain and discomfort.

4.2. Results in context of ERAS programmes

We obtained no data on urinary retention or length of stay. However, a case-control study that evaluated vaginal packing together with other interventions within an ERAS programme concluded that packing might negatively affect both hospital stay and costs (18). The study group comprised women undergoing vaginal hysterectomy who had been enrolled in an ERAS program where the standard practice was not to pack the vagina. After reviewing the results of packing together with other interventions within ERAS pathways for vaginal hysterectomy, Kalogera et al. (19) and Jeppson et al. (22) came to the same conclusions.

Though we could not obtain data on the effect of vaginal packing alone on urinary retention and length of admission, it seems logical that any impact of vaginal packing on bladder emptying will be negative. A tight gauze in the vagina can be expected to exert compression on the bladder neck and urethra, thus making

it difficult to void spontaneously. Due to this belief, many surgeons prefer to place an indwelling bladder catheter while the vagina remains packed, with both interventions usually performed in tandem and likely to present barriers to early discharge.

Overall, we found that the intervention offered no clear benefit for the predefined outcomes.

4.3. Strengths and limitations

The quality of available studies limited this review. Very few evaluated the intervention itself, and uncertainty hampered the interpretation of their results. We rated the overall quality of the evidence as moderate. Most interventions were assessed based on two or three randomized controlled trials for which the evidence quality ranged from low to moderate. The main limitation in this body of evidence was imprecision, mainly due to small sample sizes, variability in outcome measures, and low event rates. Hence, it was not possible to pool the data (except for blood loss) and the interpretation of results was difficult. Despite these limitations, we believe the common elements in studies comparing the intervention against its alternative coupled with the data from ERAS pathway evaluation provide a good foundation upon which to build an evidence-based recommendation. These allowed the panel to discuss the predefined outcomes in the PICOS framework and reach agreement to formulate the recommendation.

4.4. Implications for practice

The recommendation provides surgeons with evidence-based reasons to avoid routine vaginal packing in the postoperative management of women undergoing vaginal hysterectomy. This can result in a shorter length of stay if performed within an ERAS protocol.

5. Conclusions

The working group agreed that a routine recommendation should favour minimal intervention in the absence of a clear benefit in favour of the intervention. Given that the systematic review of the literature indicated that routine vaginal packing after vaginal hysterectomy (with or without colporrhaphy) offered no clear benefit, we advise against routinely performing this procedure. However, vaginal packing may still be considered when a surgeon determines that haemostasis cannot be ensured.

Disclosure of interests

The authors declare that they have no conflict of interest.

Contributions to authorship

Oriol Porta Roda, Ariana Cornet Cortada, Albert Font Vilamitjana, Eva Huguet Galofré, and Judith Lleberia Juanós designed the criteria for revision. Ivan Solà performed the systematic revision and data extraction. Oriol Porta Roda, Ariana Cornet Cortada, Albert Font Vilamitjana, Eva Huguet Galofré, Judith Lleberia Juanós, and Ivan Solà analysed the data. Oriol Porta Roda, Ariana Cornet Cortada, Albert Font Vilamitjana, Eva Huguet Galofré, and Judith Lleberia Juanós wrote the manuscript. Ivan Solà critically revised the manuscript. All authors approved the final manuscript as submitted.

Details of ethics approval

Not required.

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Figure 1. Prisma Flowchart

Table 1. Characteristics from Included Trials

STUDY	POPULATION	INTERVENTION	OUTCOMES	RISK OF BIAS
Westermann	77 women	Intervention	Primary · Pain	Randomization
2016	undergoing vaginal	cotton gauze	(vas 0 (no pain) to	Low risk (sequential
	hysterectomy with	(2"*15'), that was	100 (severe pain))	number
	prolapse repairs	tightly packed into	Secondary ·	randomization
		the vagina at the	Satisfaction after	concealed by sealed,
		completion of the	surgery (vas 0 (no	opaque envelopes)
		surgical procedure	satisfied) to 100	Blinding Low risk
		Control no packing	(very satisfied)) ·	(participants and
		Co-	Bother attributable	outcome assessors
		intervention(s) all	to the vaginal	were blinded to the
		women received	packing (vas 0 (not	intervention, all
		controlled analgesia	bothersome) to 100	women responded
		for breakthrough	(very bothersome))	to vas assessments)
		pain as required	· Postoperative	Follow up,
		and had indwelling	vaginal blood loss	Complete Other,
		transurethral	-	n/a Overall , low
		catheters overnight		risk

STUDY	POPULATION	INTERVENTION	OUTCOMES	RISK OF BIAS
Thiagamoorthy 2013	173 women undergoing vaginal hysterectomy with prolapse repairs	Intervention cotton gauze (7.5 m*10 cm) soaked in proflavine antiseptic solution, that was tightly packed into the vagina at the completion of the surgical procedure Control no packing Co- intervention(s) all women had an indwelling Foley catheter until the following morning and received analgesia for breakthrough pain Surgeons could decide to place a pack at discretion regardless of the	Primary · Pain (short-form McGill Pain Questionnaire) Secondary · Infective and haematological postoperative morbidity	Randomization Low risk (randomization concealed by sealed envelopes) Blinding Low risk (participants and outcome assessors were blinded to the intervention, responded questionnaires before packing removal) Follow up, Complete Other, n/a Overall, low risk
Urzua 2013	144 women undergoing vaginal hysterectomy	randomization Intervention gauze soaked in povidone iodine for 24 h. Control no packing Co- intervention(s) all women received antibiotic prophylaxis (cefazolin, 1 g i.v.), had an indwelling Foley catheter for 24 h and received analgesia for breakthrough pain	Primary · Postoperative vaginal blood loss Secondary · Pain (vas 0 (no pain) to 10 (severe pain)) · Postoperative complications (DINDO II or higher)	Randomization Unclear (described as randomized) Blinding Unclear (blinded outcome assessment reported) Follow up, Unclear Other trial reported as conference abstract Overall unclear risk

STUDY	POPULATION	INTERVENTION	OUTCOMES	RISK OF BIAS
Baumgarten 2010	43 women undergoing vaginal surgery	Intervention vaginal packing Control no packing Co- intervention(s) not described	· Postoperative complications (bleeding or infection) The trial report did not discriminate primary or secondary outcomes	Randomization Unclear (described as randomized) Blinding High (described as open trial) Follow up, Unclear Other, trial reported as conference abstract Overall, unclear risk

Table 2 summarizes the findings from the systematic review of the outcomes of interest. We did not identify studies evaluating the impact of the intervention on acute urinary retention or hospital length of stay.

Table 2. Summary of Findings for Outcomes of Interest

Outcome	No. of studies	Quality of evidence	Impact
Vaginal bleeding	2 clinical trials	??OO LOW (Effect estimates from studies were inconsistent and imprecise)	A study of 77 women showed greater postoperative blood loss in the group receiving vaginal packs [Westermann, 2016]. An additional study of 173 participants found a similar rate between groups (RR 0.34; 95%CI 0.14–8.16) [Thiagamoorthy, 2013]

Outcome	No. of studies	Quality of evidence	Impact
Postoperative pain	3 clinical trials	???O MODERATE (Effect estimates from studies were imprecise)	A study of 77 women found no differences in postoperative pain visual analogue scale (VAS) scores in the early postoperative of predischarge periods. More women in the control group needed ketorolac analgesia [Westermann, 2016] The study of 173 women found no differences in McGill Pain Questionnaire scores the morning after the surgical procedure [Thiagamoorthy, 2013] Another study found no differences in VAS scores 24 h after surgery [Urzua,
Mid-term complications	3 clinical trials	???O MODERATE (Effect estimates from studies were imprecise)	Haematoma (3.3% versus 6.7%; RR 0.53 95%CI 0.22–1.31) In another study involving 43 women, there was a greater proportion (not significant) of women with urinary tract infection in the packing group (9.1% versus 0.0%; RR 0.23, 95%CI 0.03–1.96) [Baumgarten, 2011] In the study of 173 participants, a similar proportion of women suffered from urinary infection in each group (9.3% versus 10.3%; RR 0.88, 95%CI 0.35–2.17) [Thiagamoorthy, 2013]

Table 3. EtD Framework for the Formulation of a Recommendation

CLINICAL QUESTION: Is it necessary to place a vaginal pack after vaginal hysterectomy? POPULATION OF IS THE PROBLEM A PRIORITY? Yes Research evidence and remarks from the panel Vaginal hysterectomy

HOW SUBSTANTIAL ARE THE DESIRABLE ANTICIPATED EFFECTS? Moderate HOW SUBSTANTIA WHAT IS THE OVERALL CERTAINTY OF THE EVIDENCE OF THE EFFECTS? Moderate Research evidence and remarks from the panel vaginal hystorecomy.

CLINICAL QUESTION: Is it necessary to place a vaginal pack after vaginal hysterectomy? POPULATION (
IS THERE MAJOR UNCERTAINTY ABOUT OR VARIABILITY IN HOW MUCH PROPIE VALUE TO

IS THERE MAJOR UNCERTAINTY ABOUT OR VARIABILITY IN HOW MUCH PEOPLE VALUE TO DOES THE BALANCE BETWEEN DESIRED AND UNDESIRED EFFECTS FAVOUR THE INTERVENTION ACCEPTABLE TO KEY STAKEHOLDERS (POPULATION, PROFESSIONADOES THE COST-EFFECTIVENESS OF THE INTERVENTION FAVOUR THE INTERVENTION OR

Supplement: Search Strategies

MEDLINE (via PubMed), searched 11/03/2022

- 1 "Hysterectomy, Vaginal" [Mesh] 3,044
- 2 pelvic floor surgery[tiab] 244
- 3 pelvic floor repair[tiab] 215
- 4 pelvic reconstructive surgery[tiab] 370
- 5 vaginal hysterectom*[tiab] 3,686
- 6 vaginal surgery[tiab] 880
- 7 vaginal reconstructive surgery[tiab] 85
- 8 (vaginal[ti] OR pelvic floor[ti]) AND surgery[ti] 1,224
- 9 prolapse surgery[tiab] 1,247
- 10 #1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 7,639
- 11 "Tampons, Surgical" [Mesh] 1,545
- 12 "Surgical Sponges" [Mesh] 3,623
- 13 vaginal pack*[tiab] 126
- 14 #11 OR #12 OR #13 5,267
- $15 \# 10 \text{ AND } \# 14 \ 26$

Cochrane Central Register of Controlled Trials (The Cochrane Library), Issue 2 of 12, February 2022, $searched\ 11/03/2022$

- #1 MeSH descriptor: [Hysterectomy, Vaginal] explode all trees 275
- #2 ((pelvic NEXT floor) NEAR/5 surgery):ti,ab 180
- #3 ((pelvic NEXT reconstructive) NEAR/5 surgery):ti,ab 158
- #4 (vaginal NEAR/5 surgery):ti,ab 575
- #5 (vaginal NEAR/3 hysterectom*):ti,ab 894
- #6 (prolapse NEAR/5 surgery):ti,ab 695
- #7 #1 OR #2 OR #3 OR #4 OR #5 OR #6 2014
- #8 MeSH descriptor: [Tampons, Surgical] explode all trees 117
- #9 MeSH descriptor: [Surgical Sponges] explode all trees 240
- #10 (vaginal NEAR/5 pack*):ti,ab 51
- #11 #8 OR #9 OR #10 401

$\#12\ \#7\ AND\ \#11\ 23$

EMBASE (embase.com), searched 11/03/2022

- #1 'vaginal hysterectomy'/exp AND [embase]/lim 7240
- #2 ((pelvic NEXT/1 floor NEXT/5 surgery):ti,ab) AND [embase]/lim 839
- #3 ((pelvic NEXT/3 reconstructive NEXT/5 surgery):ti,ab) AND [embase]/lim 1416
- #4 ((vaginal NEXT/5 surgery):ti,ab) AND [embase]/lim 2851
- #5 ((vaginal NEXT/3 hysterectom*):ti,ab) AND [embase]/lim 5540
- #6 ((prolapse NEXT/5 surgery):ti,ab) AND [embase]/lim 3371
- #7~#1 OR #2 OR #3 OR #4 OR #5 OR #6~14406
- #8'surgical tampon'/exp AND [embase]/lim53
- #9 'surgical sponge'/exp AND [embase]/lim 1254
- #10 ((vaginal NEXT/5 pack*):ti,ab) AND [embase]/lim 324
- #11~#8 OR #9 OR #10~1628
- #12~#7 AND #11~76